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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,531	11/28/2000	James F. Young	10271-021-999	7010

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EXAMINER

BROWN, STACY S

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,531

Applicant(s)

YOUNG ET AL.

Examiner

Stacy S Brown

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 26, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 179-287 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☒ Claim(s) See Continuation Sheet is/are ~~allowed~~ allowable. 8/26 2/20/03
- 6) ☒ Claim(s) 1,5,179,180,206 and 280-287 is/are rejected.
- 7) ☒ Claim(s) 179 and 279 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14. 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 4,185,188,196,197,199,200,202,203,213-221,228-230,246-248,264-275 and 277-278.

Continuation of Disposition of Claims: Allowable claims are 3,181-184,186,187,189-195,198,201,204,205,207-212,222-227,231-245,249-263 and 276.

DETAILED ACTION

1. Applicant's election of Group I, drawn to antibodies that bind RSV, is acknowledged and entered. Claims 1, 3-5 and 179-287 are pending. Claims 4, 185, 188, 196, 197, 199, 200, 202, 203, 213-221, 228-230, 246-248, 264-275 and 277-278 are withdrawn from consideration being drawn to non-elected species.

The species election regarding the construct of the RSV antibody is as follows:

- VH domain, SEQ ID NO: 48
 - VH CDR1, SEQ ID NO: 10
 - VH CDR2, SEQ ID NO: 18
 - VH CDR3, SEQ ID NO: 19
- VL domain, SEQ ID NO: 20
 - VL CDR1, SEQ ID NO: 21
 - VL CDR2, SEQ ID NO: 22
 - VL CDR3, SEQ ID NO: 6

The following sets of claims are drawn to antibodies having the same sequence constructs according to the election of species. (For example, Claims 187 and 190 have SEQ ID Nos: 10 and 19):

187 and 190	235 and 226
189 and 191	232 and 238
192 and 194	244 and 253
222 and 240	245 and 254
224 and 227	250 and 256
231, 237, 249 and 255	251 and 257
225, 234, 243 and 252	

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2. The elected claims have been examined and the antibodies having the elected sequences are free of the prior art. The only pending rejections are obviousness type double patenting with co-pending US applications, see rejections below. Upon further review of the species election, the Office will not examine additional sequences due to the burdensome search on the part of the examiner and the sequence search resources at the USPTO. However, the Office will allow all antibody claims drawn to the elected sequences. Applicant is invited to submit new claims that reflect the species election and eliminate other species. The new claims may be drawn to any combination of the elected species, provided that none of the claims are drawn to an antibody having SEQ ID NO: 6 alone, since palivizumab (Synagis™) has SEQ ID NO: 6.

Claim Objections

3. Claims 179 and 279 are objected to because of the following informalities: antibodies AFF and A13C4 are claimed. In the specification, table 2, there is reference to an antibody "AFFF" and "A13c4". The Office has interpreted these differences to be a result of typos. Clarification is requested.

Double Patenting

4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

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A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

5. Claim 180 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 55 (originally mis-numbered as claim 54) of copending Application No.

09/771,415. Claim 180 of the instant application is drawn to an isolated antibody that immunospecifically binds an RSV antigen. Claim 55 of the co-pending application is drawn to an isolated neutralizing antibody. The antibody of claim 180 has neutralizing activity according to the specification and therefore is identical to the antibody of claim 55 of the co-pending application. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim 180 is directed to the same invention as that of claim 55 of commonly assigned 09/771,415. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

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6. Claims 1, 5, 179 and 280-287 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 55 (originally mis-numbered as claim 54) of copending Application No. 09/771,415. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are drawn to antibodies that have SEQ ID NO: 10 (SEQ ID NO: 9 in the co-pending application). Claim 55 of the co-pending application is a species of claims 1, 5, and 179 of the instant application. Claim 55 recites the specific CDR position. Claims 1, 5 and 179 recite the same sequence as claim 55 without reciting the specific CDR position. Claims 280-287 are drawn to obvious limitations of the isolated antibody of claim 55, evidenced by palivizumab (Synagis™), see US Patent 5,824,307.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1, 180, 206, 283 and 286 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 4, 15, 36 and 73 of copending Application No. 09/996,288. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 280-282 and 284-287 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 73 of copending Application No. 09/996,288 in view of US Patent 5,824,307 (Johnson). Claim 73 is drawn to a pharmaceutical composition, the limitations of which are disclosed in Johnson in the use of palivizumab (Synagis™).

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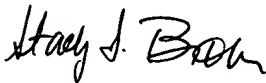
This is a provisional obviousness-type double patenting rejection.

Conclusion


8. SEQ ID NO: 48, 10, 18, 19, 20, 21 and 22 are free of the prior art.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stacy S. Brown
February 20, 2003



HANKYEL T. PARK, PH.D
PRIMARY EXAMINER